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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,451	12/19/2003	David S.F. Young	2056.027	8152

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,451	YOUNG ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/19/03; 3/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed 19 December 2003 has been entered in full.

2. Claims 1-54 are cancelled.

3. Claims 55-62 are pending and under examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 19 December 2003 and 05 March 2004 have been fully considered by the examiner.

Specification

5. The first line of the specification needs to be updated with the US Patent number for USSN 10/348,231, field 1/21/2003. The US Patent number is 7,009,040.

6. This application repeats a substantial portion of prior Application No. 10/348,231, filed 1/21/2003, and adds and claims additional disclosure not presented in the prior application (e.g., see pg. 13 of the specification and item no. 14 below). Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Accordingly, the first line of the specification should be updated to indicate that the present application is a CIP of 10/348,231, filed 1/21/2003, now U.S. Patent 7,009,040.

7. The use of the trademark CellQuest™ has been noted in this application. See pg. 22, line 10 of the specification. It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicant's cooperation is requested in reviewing the entire disclosure for additional trademarks that require correction.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

8. Applicant's cooperation is requested in reviewing and correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Deposit of Biological Material

9. It is noted that the claimed invention relies on a biological material (i.e., clone/hybridoma deposited with the ATCC as Accession Number PTA-4890) requiring a biological deposit to satisfy the statutory requirements for patentability under 35 U.S.C. 112 (enablement). Applicant's referral to the hybridoma deposit (PTA-4890) on page 13 of the specification that the hybridoma cell line 7BD-33-11A was deposited in accordance with the Budapest treaty with the ATCC, 10801 University Blvd., Manassas, VA 20110-2209 on January 8, 2003 under Accession Number PTA-4890 and that *all restrictions imposed on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent*, is acknowledged. Therefore, a

biological deposit rejection for the hybridoma deposited with the ATCC as Accession Number PTA-4890 is obviated.

10. The examiner acknowledges the terminal disclaimer filed 9/16/2005 and approved on 4/28/2006 to obviate a double patenting rejection over US Patent 7,009,040 (USSN 10/348,231).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.**

12. Claims 55-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 55-62 are indefinite in the recitation "monoclonal antibody encoded by the clone deposited with the ATCC as Accession Number PTA-4890" in claims 55 and 56. The specification discloses that the hybridoma cell line 7BD-33-11A was deposited with the ATCC as accession number PTA-4890 (see pg. 13). Thus, it is unclear what is contemplated by the phrase "monoclonal antibody encoded by the clone deposited with the ATCC as Accession Number PTA-4890", in view that the art teaches that a hybridoma is produced by the fusion between a B cell and a myeloma cell, which is a cancer cell that provides the resultant B cell-myeloma hybrid, or hybridoma, with the capacity to proliferate indefinitely where the hybridoma produces mouse antibodies of a single idiotype (i.e., the monoclonal antibodies produced from a given hybridoma are

identical) (see Campbell et al, Biology, 5th ed. pg. 856, 1999). Are there other monoclonal antibodies encoded by the clone PTA-4890, is the clone genetically engineered such that other forms of monoclonal antibodies including chimeric and humanized monoclonal antibodies (as recited in dependent claims 61-62) are "encoded" by the clone PTA-4890 or is the clone actually a hybridoma that secretes or produces monoclonal antibody 7BD-33-11A? What other monoclonal antibody or antibodies other than monoclonal antibody 7BD-33-11A are "encoded" by the clone deposited with the ATCC as PTA-4890 as presently claimed? As written, one skilled in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Amending the phrase "monoclonal antibody encoded by the clone deposited with the ATCC as Accession Number PTA-4890" to recite "monoclonal antibody produced by the hybridoma deposited with the ATCC as Accession Number PTA-4890" would overcome this rejection.

b. Claims 55-62 are indefinite in the recitation "or a cellular cytotoxicity inducing antigen binding fragment thereof" in claims 55 and 56. Is the cellular cytotoxicity inducing antigen-binding fragment thereof an antigen-binding fragment of the deposited monoclonal antibody (PTA-4890) or is the cellular cytotoxicity inducing antigen-binding fragment thereof an antigen-binding fragment of the isolated monoclonal antibody that binds the same epitope as the deposited monoclonal antibody (PTA-4890)?

c. Claims 56-62 are indefinite in reciting the limitation "said monoclonal antibody or said antigen-binding fragment thereof" in claim 56 and "said monoclonal antibody" in claims 57 and 59-62. There is insufficient antecedent basis for these limitations in the

claims. Claim 56 recites two different monoclonal antibodies, the monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890 and a monoclonal antibody which binds the same epitope as the monoclonal antibody produced by the hybridoma deposited with the ATCC as accession number PTA-4890, making it uncertain which of the two monoclonal antibodies was intended. See MPEP 2173.05(e).

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 55-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a "new matter" rejection.

The preliminary amendment filed 9/16/2005 has introduced "new matter" into the claims. As amended, the claims recite a method for initiating antibody induced cellular cytotoxicity of cancerous cells in a tissue sample and a method of treating a human tumor susceptible to antibody induced cellular cytotoxicity, each method comprising a providing or administering a monoclonal antibody or antigen-binding fragment thereof that binds to the same epitope as the monoclonal antibody produced by the hybridoma

deposited with the ATCC as accession number PTA-4890. As originally filed, the claims were drawn to methods of treating a human tumor in a mammal and binding assays for the detection of cancerous cells in a tissue sample, each method using the monoclonal antibody produced by the hybridoma deposited with the ATCC as PTA-4890 or a monoclonal antibody having the identifying characteristics of the monoclonal antibody produced by the hybridoma deposited with the ATCC as PTA-4890. There is insufficient written support for the presently claimed methods using a subgenus of monoclonal antibodies that bind to the same epitope as the monoclonal antibody produced by hybridoma PTA-4890. There is insufficient guidance and direction to lead one of skill in the art from the genus of antibodies having the "identifying characteristics" of the deposited antibody (PTA-4890) to the presently claimed subgenus of antibodies that bind the same epitope as the deposited antibody because the "identifying characteristics" were not adequately disclosed, as-filed. Thus, the specification as filed does not clearly disclose or provide adequate guidance and direction to the presently claimed subgenus of monoclonal antibodies that bind the same epitope as the monoclonal antibody produced by the hybridoma deposited with the ATCC as PTA-4890. Applicant's reliance on a generic disclosure and possibly a single species has not provided sufficient direction and guidance to the features currently claimed. It cannot be said that a subgenus is necessarily described by a genus encompassing it (i.e., "identifying characteristics") and a species (i.e., monoclonal antibody 7BD-33-11A) upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Obviousness is not the standard for the addition new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter, which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

SHEELA HUFF
PRIMARY EXAMINER